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(33) Priority Country: US

(71) Applicant: VASCUTEC INC. [US/US]; 375 Engle Street, Englewood, NJ 07631 (US).

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(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent).

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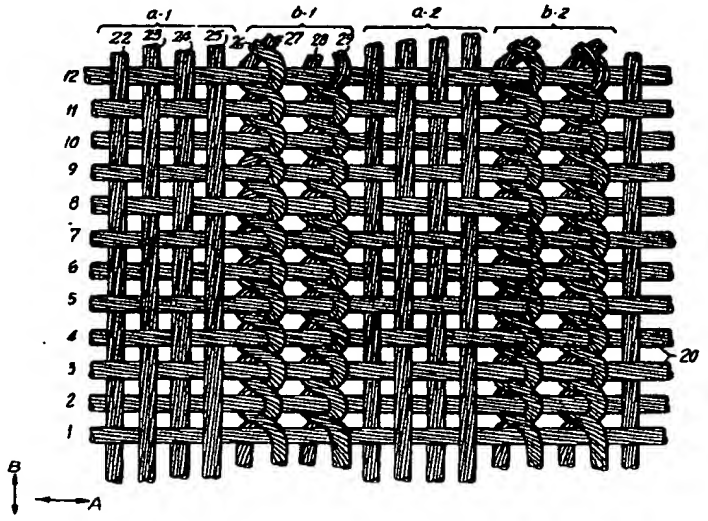

(57) Abstract

A woven vascular graft having alternating plain/twill weave and two pairs of double leno weave is disclosed. Conventional knitted grafts are flexible soft and conforming, but require preclotting because the porosity is too great. Conventional woven grafts have low porosity and do not need preclotting but are stiffer and less conforming than knit grafts. The new vascular graft of this invention has low porosity as in other woven grafts, yet the pliability is similar to extruded grafts. The inventive weave pattern has fill threads (20), warp twill weave threads (23) and (25), plain warp threads (22) and (24), and two adjacent pairs of double leno threads (26), (27) and (28), (29).

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[Received by the International Bureau on 23 January 1989 (23.01.89); original claims 1-13 cancelled; new claims 14-31 added (4 pages)]

14. A vascular graft prosthesis comprising a tube formed of woven fabric and attachable into the vascular system for conveyance of blood therethrough, the fabric being a weave having a plurality of warp threads running in the axial direction of the tube and a plurality of weft threads running in a transverse direction to said axial direction, said warp threads being in sets of lenos and sets of plain and twill threads, the sets being in a repeating sequence where each set of lenos is followed by a set of plain and twill threads, and where each leno comprises a pair of warp threads crossed one over the other between weft threads, each set of lenos comprises at least two adjacent lenos, and each set of plain and twill threads comprises at least four alternating plain and twill threads, the twill threads forming velour loops only on one surface of said fabric which fabric as a vascular graft has a resulting porosity that permits endothelization and substantially prevents hemorrhaging.

15. A graft according to claim 14 wherein said threads comprise texturized 64 denier/144 filament polyester.

16. A graft according to claim 14 wherein said weave pattern when initially woven comprises warp threads in the range of 140 to 170 threads per inch and weft threads in the range of 60 to 80 threads per inch.

17. A graft according to claim 14 wherein all said warp and weft threads except the velour threads are not pre-shrunk before being woven.

18. A graft according to claim 4 wherein said weave after shrinkage comprises warp threads in the range of 140 to 170 threads per inch, and weft threads in the range of 70 to 80 threads per inch.

19. A graft according to claim 14 wherein all said threads are texturized to have about 1 1/2 turns per inch of length.

20. A graft according to claim 14 wherein each plain/twill set comprises 3/1 twill threads alternating

with 1/1 plain threads.

21. A graft according to claim 14 wherein each plain/twill set comprises between 4 and 8 warp threads wov n in alternating 1/1 plain and 3/1 weave.

22. A graft according to claim 14 wherein for each of the plain/twill sets one of the plain strands is advanced longitudinally by one weft strand relative to the next plain strand.

23. A graft according to claim 14 wherein said tube comprises a first part of first diameter, and one end of said first part is bifurcated and extends as two tubes of diameter smaller than said first diameter.

24. A graft according to claim 14 wherein said threads comprise texturized 75 denier /72 filament polyester yarn.

25. A graft according to claim 14 wherein said fabric has a flat interior surface and a velour loop exterior surface to receive tissue ingrowth.

26. A graft according to claim 14 wherein each of said filaments comprises polyethylene terephthalate weighing less than 1.0 gram per 9,000 meters.

27. A graft according to claim 14 wherein each of said filaments comprises polyethylene terephthalate weighing from 0.4 grams to 1.0 gram per 9,000 meters.

28. A woven fabric adapted for use in a vascular prosthesis for implantation into a living body, the fabric being a weave having a plurality of warp threads running in the axial direction of the tube and a plurality of weft threads running in a transverse direction to said axial direction, said warp threads being in sets of lenos and sets of plain and twill threads, the sets being in a repeating sequence where each set of lenos is followed by a set of plain and twill threads, and where each leno comprises a pair of warp threads crossed one over the other between weft threads, each set of lenos comprises at least two adjacent lenos, and each set of plain and twill threads comprises at least four alternating plain and twill

threads, the twill threads forming velour loops only on one surface of said fabric which fabric as a vascular graft has a resulting porosity that permits endothelization and substantially prevents hemorrhaging.

29. A fabric according to claim 28, wherein said warp threads and said weft threads texturized 64 denier/144 filament polyester.

30. A fabric according to claim 28, wherein said warp threads and said weft threads comprise texturized 75 denier/72 filament polyester.

31. A fabric according to claim 28, wherein each plain/twill set comprises between 4 and 8 warp threads in alternating 1/1 plain and 3/1 twill weave.

32. A vascular graft prosthesis comprising a tube formed of woven fabric and attachable into a vascular system for conveyance of blood therethrough, the fabric being a weave having a plurality of warp threads running in the axial direction of the tube and a plurality of weft threads running in a transverse direction to said axial direction, said warp threads being in sets of lenos and sets of plain and parallel twill threads, the sets being in a repeating sequence where each set of lenos is followed by a set of plain and parallel twill threads, and where each leno comprises a pair of warp threads crossed one over the other between weft threads, each set of lenos comprises at least two adjacent lenos, and each set of plain and parallel twill threads comprises at least four alternating plain and parallel twill threads, the parallel twill threads forming velour loops only on one surface of said fabric which fabric as a vascular graft has a resulting porosity that permits endothelization and substantially prevents hemorrhaging.

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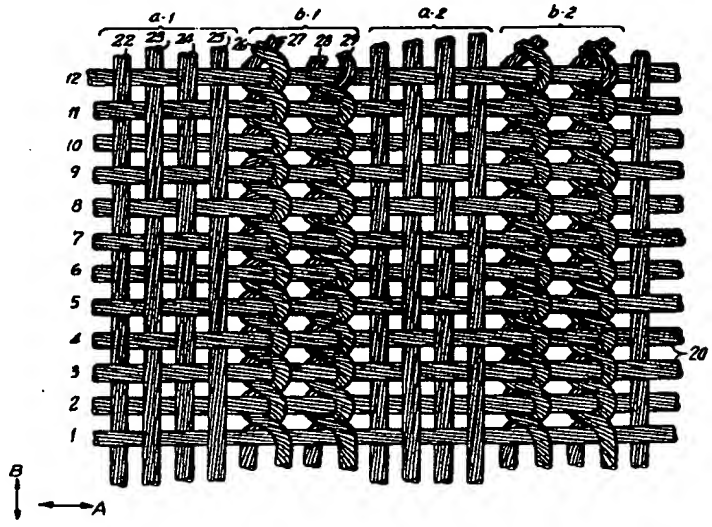

(57) Abstract

A woven vascular graft having alternating plain/twill weave and two pairs of double leno weave is disclosed. Conventional knitted grafts are flexible soft and conforming, but require preclotting because the porosity is too great. Conventional woven grafts have low porosity and do not need preclotting but are stiffer and less conforming than knit grafts. The new vascular graft of this invention has low porosity as in other woven grafts, yet the pliability is similar to extruded grafts. The inventive weave pattern has fill threads (20), warp twill weave threads (23) and (25), plain warp threads (22) and (24), and two adjacent pairs of double leno threads (26), (27) and (28), (29).

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ARTERIAL GRAFT

BACKGROUND OF THE INVENTION

This invention is in the field of vascular grafts made of synthetic fibers that are used in a variety of vascular surgical procedures. Particular interest herein is to grafts used to replace occluded portions of arteriosclerotic vessels or used to form new blood pathways in vascular reconstruction procedures, as generally disclosed in U.S. patent Nos. 4,517,687, 4,047,252, 4,530,113, and 3,878,565.

There are basically three kinds of grafts on the market, namely extruded, knitted and woven. Extruded or non-woven grafts are generally strong and non-porous which precludes subsequent hemorrhaging, but have numerous undesirable characteristics. The total lack of porosity prevents subsequent tissue ingrowth which has been considered highly desirable. Also these grafts are relatively stiff and nonconforming and thus difficult to handle and implant.

Knitted grafts have numerous advantages over the extruded ones, namely high porosity, flexibility, softness and a velour type surface. Accordingly, they conform easily which reduces surgeon's and patient's time in the operating room, and the porosity and velour surface allow considerable endothelization (tissue ingrowth). The principal disadvantage of knitted grafts is that the porosity is so great, hemorrhaging will occur unless the graft is preclotted, this being a separate step requiring about fifteen minutes for immersion of the graft in a quantity of

about 100-150 cc of blood of th patient, after which the graft is allowed to stand for clotting to occur. Preclotting substantially prevents hemorrhaging, while tissue ingrowth can still proceed; however sometimes preclotting is not permissible as where the patient has been anti-coagulated or has bleeding diathesis. In these cases a knit graft cannot be used. Final negative considerations about knitted grafts are the recent belief that the high velour interior surface inherent in knit fabric may simply act to collect dead tissue and disrupt blood flow, that tissue ingrowth into the high velour exterior surface may be less significant than previously predicted, and that knitted grafts expand and stretch more than other types.

Woven grafts have certain advantages over both extruded and knitted grafts in that porosity is lower, so that preclotting is not required and the surfaces are more uniform for smoother blood flow. A disadvantage of woven grafts is that they are relatively stiffer and less conforming than knit grafts and thus more difficult and time consuming for the surgeon to use.

A prospective and not currently available graft is a knitted tube coated in manufacture with a substance such as collagen to prevent initial bleeding following implanation. This collagen coating obviates the necessity for typical preclotting during surgery; however, such coating renders the tube stiffer and more difficult to handle during implantation. Also such a coated product is considerably more expensive than a simple woven graft.

The above description of prior art grafts shows som of the numerous parameters considered in the selection of vascular grafts. Additional factors include tissue compatibility, nonthrombogenicity of the surface, deterioration of the graft with time, resistance to infection, and resistance to kinking at the joints of the patient.

Typically in the manufacture of both knitted and woven grafts the tubular body is crimped to form circumferential corrugations or ribs that provide strength and resilience against kinking and collapsing of the tube and narrowing of the lumen from bending or twisting. Known woven grafts use a polyester such as Dacron^{R} (polyethylene terephythalate) yarn, Type 56 made by Dupont for approximately 30 years and designated 40 denier/27 or 70 denier/34, the 40d/27 representing 40 grams of weight per 9000 meters of yarn which yarn comprises 27 filaments, or 1.48 denier per filament. Dacron^{R} is a registered trademark for E.I. Dupont for polyester yarn. The selection of 40d/27 yarn in single or double ply as the standard of the industry has been dictated by what was available on the market and what has been approved by the F.D.A. Prior patents referred to above describe more fully this standard yarn, which is also texturized in a standard way, i.e. twisting the fibers at about 250,000 rpm, under 8-15 grams of tension at about 450^{o}F.

The weaving of arterial grafts is done on known weaving apparatus with a matrix of weft or fill threads into which are

woven a pattern of warp threads, some of which are twill or velour weave to later produce the velour loops on the inner and/or outer surfaces. As is known, these twill threads are preshrunk, so that upon the shrinking of the completed graft tube made of otherwise unshrunk yarn, all threads will shrink except the velour ones which will extend outward from the surface as loops to subsequently receive the tissue ingrowth.

In view of the above-described function parameters and the differences between the various prior art grafts, compromises in characteristics are required with each selection. More specifically, if one wishes softness and pliability and porosity, the choice must be a knit graft with the required preclotting.

SUMMARY OF THE INVENTION

The new vascular graft of this invention provides a combination of critical advantages that have been previously available only partially with knit grafts and partially with woven grafts. More particularly the new graft has the low porosity of woven grafts, the softness and pliability of knits, and the non-fraying feature of extruded grafts. This has become possible by the selection of a high denier, high filament or lower denier, higher filament (75d/72 and 64d/144) polyester yarn which is texturized under new conditions, and woven in a new weave pattern. The weave is designed as a double leno-twill weave with repeating sets of double-lenos, with a flat interior surface and a velour outer surface to aid in healing via

ndothelization. The weave includes repeating sets of double leno and plain/twill threads, where each double leno set comprises at least two pairs of twisted or crossed leno threads, and each plain/twill set comprises at least four warp threads alternating as plain, twill, plain, twill. Each twill is woven typically as 3/1, i.e. at least over three fill threads following under one fill thread. The sets or pairs of double leno weaves are interspersed with the plain and twill threads to lock the weft threads, and thus substantially prevent fraying or unravelling of the fill threads when the end of the tube is cut at an oblique angle. These new woven grafts have lower porosity than knitted grafts, yet have the softness and pliability of knits and still do not require preclotting. They are thus easier to handle and implant and conform.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a section of woven vascular tube spirally crimped in accordance with this invention;

Fig. 2 is a perspective view of a section of woven vascular bifurcated graft sprially crimped in accordance with this invention;

Fig. 3 is a fragmentary plan view of a graft wall surface showing a twill-double leno and gauze weave which has been used in Fig. 1 and Fig 2;

Fig. 4 is a view similar to Fig. 3 showing the alternative method of the twill and double leno and gauze weave pattern; and

Fig. 5 is a fragmentary elevation view of the graft of Fig. 1 sutured to an artery.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A vascular graft of the present invention is shown as a segment 10 of a straight tube in Fig. 1 and as a bifurcated segment 12 in Fig. 2. Each segment has circumferential ribs 14 defining therebetween grooves 16. The tube is woven from polyester yarns into the tubular shapes shown, with the tubular wall being a weave pattern as represented by the enlarged views in Figs. 3 and 4. The black lines 18 and 19 in Figs. 1 and 2 respectively are readily visible to aid the surgeon to avoid twisting the tube during implantation. Optionally, such a line can also be radiopague to indicate more clearly in an X-ray picture the location and condition of the implanted graft. Th circular ribs, which may also be helical, add structural stability to the tube for maintaining the lumen open and reduce kinking despite curves along the axis of the graft and subsequent movement or bending of the graft after implantation.

The fabric of Figs. 3 and 4 is woven by techniques and apparatus known in industry. The novelty herein concerns the new weave pattern of a yarn that is also new by virtue of its selection and texturizing technique. This yarn and weave combination provide a tubular fabric with highly advantageous characteristics when used as an arterial graft.

The next following section will describe the new weave pattern; the yarn itself and the texturizing will be described in

later sections. To create the tubular grafts of this invention weaving apparatus known in the art is used. As represented in Fig. 3, weft or fill threads 1-12 in the direction of the arrow A are set up at about 72 picks per inch, and warp threads are woven in the direction of the arrow B at about 140-170 per inch. In the enlarged Figures 3 & 4 the threads appear widely spaced apart; however, in actuality the threads are tightly packed forming a fabric of the graft wall that is substantially non-porous to hemorrhaging or blood leakage.

The weave pattern of Fig. 3 comprises regular fill threads 20 and repeat sets of warp threads comprising from left to right, set a-1 of alternating plain gauze and twill threads, set b-1 of two pairs of double-lenos, set a-2 the repeat of a-1, and set b-2 the repeat of b-1. In set a-1 threads 22 and 24 are plain 1/1 gauze weave, i.e. over one fill thread, under the next, over the next, etc. Threads 23 and 25 are 3/1 twill weave, in that each goes under one fill thread, over the next three fill threads, under the next one fill thread, etc. More specifically, warp thread 22 goes under fill thread 1, over fill 2, under fill 3, over 4, etc., and warp (twill) thread 23 goes over fill threads 1, 2 and 3, under 4, over 5, 6 and 7, under 8, etc. Threads 23 and 25 are pre-shrunk, so that later when the tube is completed and shrunk, all the threads shrink up to tightly compact the fabric, except the pre-shrunk segments of warp threads that lie "over three fill threads" do not shrink with the

fabric but stand out from th top surfac of the fabric as velour loops to later better accommodate tissue ingrowth.

The pairs of double leno threads 26, 27 and 28, 29 in s t b-1 are woven over-under-over-under the fill threads and criss-crossed, one over the other. As represented, these sets b-1 and b-2 repeat alternately completely around the tube.

In a typical implantation the end of a tubular graft is cut at an oblique angle to produce a generally oval edge 30 as generally indicated in Fig. 1, which edge is later sutured onto an existing artery 32 as indicated in Fig. 5. An oval edge is preferred to a circular edge from a cut normal to the tube axis, because the resulting oval edge fits the existing artery better and provides a greater length of edge to be sutured and thus a more secure and reliable junction.

Because the cut edge 30 is highly angular relative to the fill or weft threads that are perpendicular to the tube axis and the warp threads, fraying or unravelling of fill threads at the cut edge results. Such unravelling is extremely unsatisfactory because this is the precise area of junction where the graft is sutured to the existing artery and where strength and consistency of the fabric is needed. The sets of double-leno by their criss-cross and twist, lock in the fill threads so that unravelling is prevented or at least minimized.

The repeated and alternating sets of plain/twill and double-leno provide a fabric matrix that has: (a) a generally

flat inner surfac , (b) velour loops at an appropriate frequency and distribution on the outer surface, and (c) locking double-lenos at sufficient frequency to greatly inhibit unravelling.

Fig. 4 is similar to Fig. 3, but differs in that warp thread 23a which corresponds generally to thread 23 in Fig. 3, is woven such that each "over three picks" loop is displaced axially by one weft thread from the corresponding loop of thread 25a. Accordingly, thread 23a lies under fill thread 4, over fill threads 5, 6 and 7, then under 8; whereas, the next warp thread 25a lies under fill 5, over fills 6, 7 and 8, and under 9. In fabrics where this axial displacement continues with each subsequent twill thread, a diagonal pattern appears in the fabric called a twill. In Fig. 3 where the warp threads 23 and 25 are not relatively displaced axially, the designation is parallel twill. The remaining plain and double-leno threads in Fig. 4 are the same as in Fig. 3.

Whether the warp thread pattern of Fig. 3 or Fig. 4 is used in making a woven graft, the inner surface will be generally flat, the outer surface will include velour loops, and the cut edge will have a greatly reduced likelihood of unravelling. It is also acceptable to vary the number of warp threads i.e. the alternating plain and twill threads, in each set a-1, a-2, etc. in Figs. 3 and 4 to comprise five, six, seven or more, so long as each set b-1, b-2, etc. comprises at least two pairs of double-lenos as shown.

The yarn used in this new fabric graft is preferably polyester (polyethylene terephthalate) of 64 denier/144 filaments available from Tejin Company of Japan. Yarn of this material is biocompatible and long lasting within the body of a patient. Because this yarn has more and thinner filaments than the traditional 40d/27 Dacron yarn (Type 56 of Dupont), each thread has greater vulnerabilty to breakage, so that new and special texturizing techniques were developed to as follows. The new texturizing parameters include: lower twist speed of 80,000-90,000 rpm compared to the standard 250,000 rpm, lower tension of 4-5 grams compared to the standard 8-15 gms, lower heat of 360°F compared to the standard 450°F and greater twists per inch of 1 1/2 compared to 1/2 turns in prior art. The new texturized yarn is adequately strong and reliable to be appropriate for these arterial grafts. The twill or velour threads are pre-shrunk by known methods.

The woven fabric of the graft may be designated 2/64/144 texturized (2 ply 64 denier 144 filaments) or 1/64/144 texturized (1 ply 64 denier 144 filaments), fabricated as a woven gauze-double leno with twill weave having velour loops only on the outside surface. After weaving is completed the new tubular grafts are processed for shrinking, which controls the density of the fabric and thus the porosity discussed above as regards tissue ingrowth and control of hemorrhaging. The final diameter of these grafts is between about 2 to 34 mm. Porosity will be

between 25 and 100 ml/min/cm^2/120mm Hg. Lastly, the circumferential ribs or corrugations are formed under heated conditions and set.

While the invention has been described in terms of certain preferred embodiments, modifications obvious to one with ordinary skill in the art may be made without departing from the teachings of the present invention.

Various features of the invention are set forth in the following claims.

WHAT IS CLAIMED:

1. A vascular graft prosthesis comprising a tube formed of fabric and attachable into the vascular system for conveyance of blood therethrough, the fabric being a weave having a plurality of warp threads running in the axial direction of the tube and a plurality of weft threads running in the circumferential direction of the tube, said warp threads being in a weave pattern comprising sets of double leno threads and sets of alternating plain and twill threads, where typically each set of plain and twill threads is between and adjacent a set of double-lenos, and where each double leno set comprises at least two adjacent pairs of crossed warp threads, and each plain and twill set comprises at least four threads in alternating order of plain, twill, plain, twill, the twill strands forming velour loops only on on surface of said fabric, which fabric as a vascular graft has a resulting porosity that permits endothelization and substantially prevents hemorrhaging, and which is substantially non-freying when cut at an angle relative to said tube axis.

2. A graft according to claim 1 wherein said threads comprise texturized 64 denier/144 filament polyesther.

3. A graft according to claim 1 wherein said weave pattern when initially woven comprises warp threads in the range of 140 to 170 threads per inch and weft threads in the range of 60 to 80 per inch.

4. A graft according to claim 1 wherein all said warp and weft threads except the velour threads are pre-shrunk before being woven.

5. A graft according to claim 4 wherein said weave after shrinkage comprises warp threads in the range of 140 to 170 threads per inch, and weft threads in the range of 70 to 80 threads per inch.

6. A graft according to claim 1 wherein all said threads are texturized to have about 1 1/2 turns per inch of length.

7. A graft according to claim 1 wherein each plain/twill set comprises 3/1 twill threads alternating with 1/1 plain threads.

8. A graft according to claim 1 wherein each plain twill set comprises between 4-8 warp threads woven in alternating 1/1 plain and 3/1 weave.

9. A graft according to claim 1 wherein the loops of one of the twill strands of each plain/twill set are displaced axially by one weft strand relative to the loops of the next following twill strand.

10. A graft according to claim 6 wherein for each of the plain/twill sets one of the plain strands is advanced longitudinally by one weft strand relative to the next plain strand.

11. A graft according to claim 1 wherein said tube comprises a first part of first diameter, and one end of said first part is bifurcated and extends as two tubes of diameter smaller than said first diameter.

12. A method of texturizing polyester 64d/144 filament yarn comprising the steps of spinning the yarn at about 80,000 to 90,000 rpm under a tension of about 5 grams with about 1 1/2 turns per inch and curing at a temperature of about 360°F.

13. A method of texturizing polyester 64 denier/144 filament polyester yarn comprising the steps of spinning the yarn at 85,000 rpm $\pm$ 10, under a tension of 5 grams $\pm$ 2, with a twist of 1 1/2 turns per inch $\pm$ 1/2, and subsequently heating said yarn at 360° F $\pm$ 15°.

FIG. 1

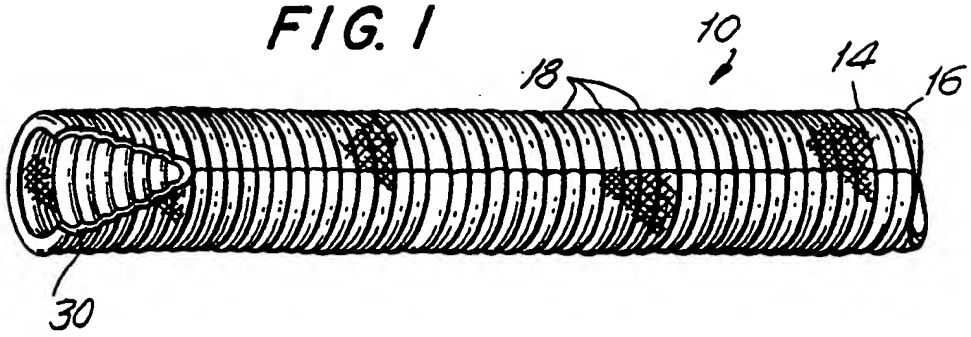


FIG. 2

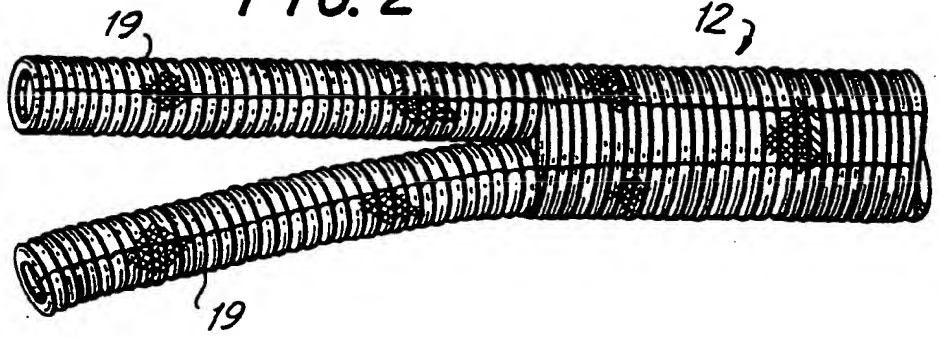
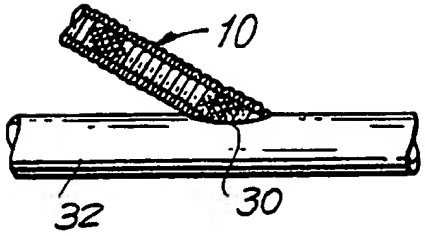


FIG. 5



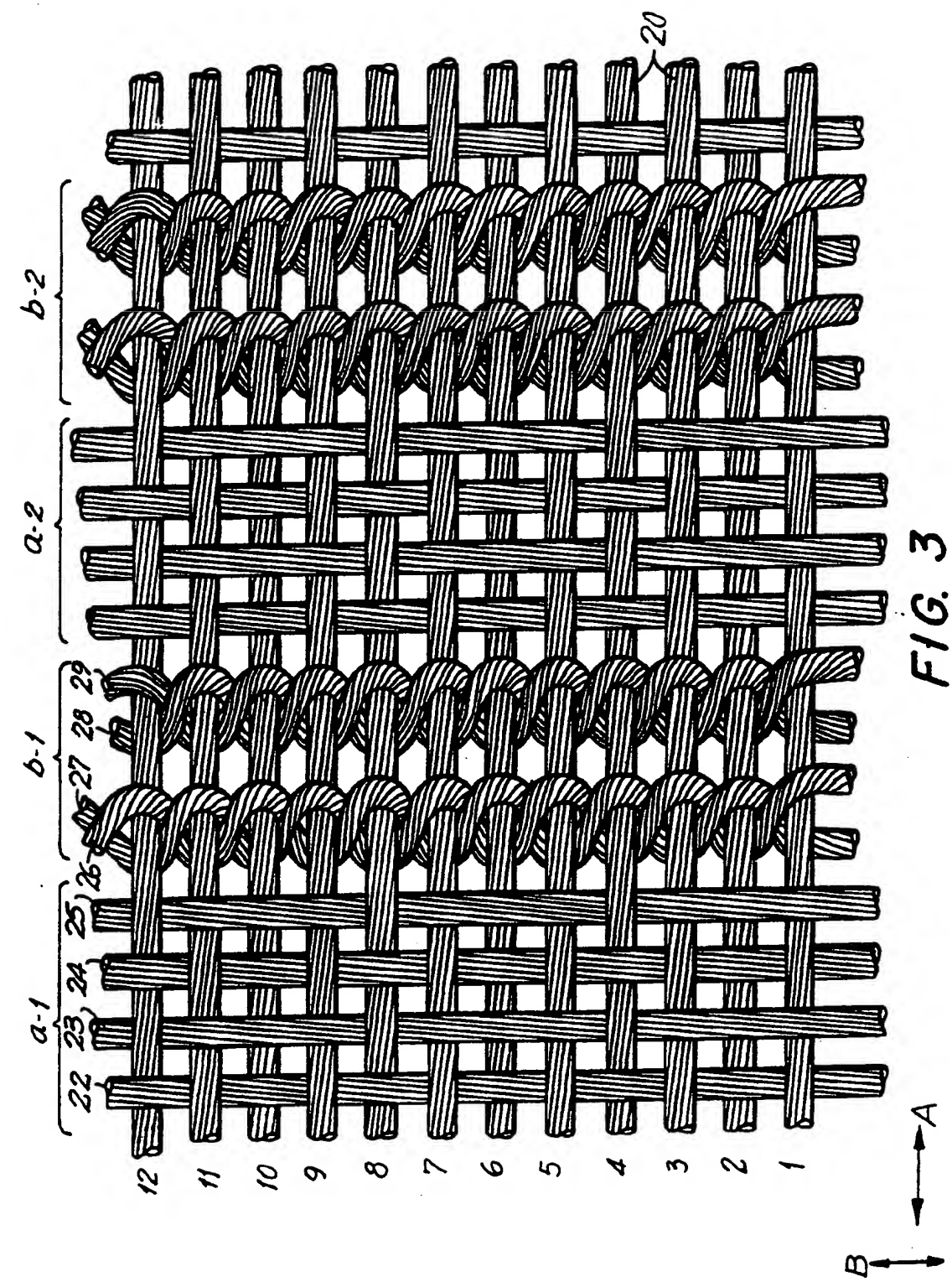


FIG. 3

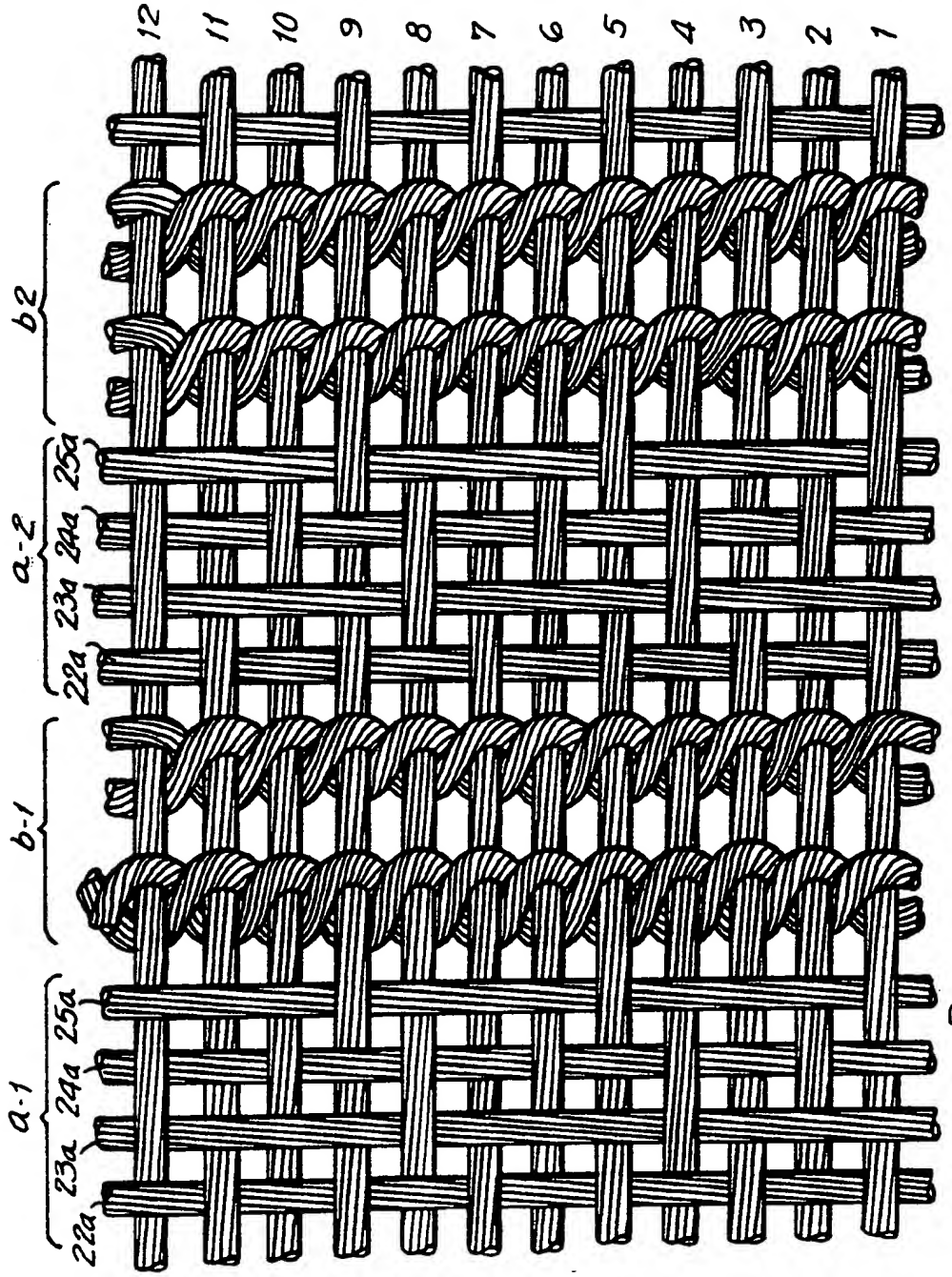


FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US88/02121

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(4): A61F 2/06
U.S. Cl. 623/1

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S. Cl.	128/334R 139/387R, 388,419 428/36, 257,258
U.S. Cl.	623/1,12,13,66 57/282,284

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	US, A 4,530,113 MATTERSON, 23 July 1985 (23.07.85) (Note Col. 1, lines 50-52; Col. 5, lines 44-66; Col. 7, lines 22-55 and Figures 2-5).	1-11
Y	US, A 4,282,011 TERPAY, 04 August 1981 (04.08.81) (Note Figures 1 and 3 and Col. 6, lines 7-35).	1-11
Y	US, A 3,878,565 SAUVAGE, 22 April 1975 (22.04.75), (Note the title; abstract; Col. 1, lines 29-30 and lines 56-60).	1-11
A	US, A 4,760,690 LANG et al, 02 August 1988, (02.08.88), (Note claim 1).	12-13

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
29 September 1988	23 NOV 1988
International Searching Authority	**Signature of Authorized Officer**
ISA/US	Paul Prebilic

Form PCT/ISA/210 (second sheet) (Rev.11-87)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☒ Claim numbers . because they relate to subject matter [12] not required to be searched by this Authority, namely:

a method of making texturized yarn (claims 12 and 13).

2. ☐ Claim numbers . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:.

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

I. Claims 1-11 drawn to the woven vascular graft classified in class 623 subclass 1.

II. Claims 12 and 13 drawn to the method of making a texturized fiber classified in class 57 subclass 282.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application. Telephone Practice (See attached sheet).

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.